

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP.,)	
INTEGRA LIFESCIENCES SALES LLC,)	
CONFLUENT SURGICAL, INC., and)	
INCEPT LLC,)	
)	
Plaintiffs,)	C.A. No. 15-819 (LPS) (CJB)
)	
v.)	PUBLIC VERSION
)	
HYPERBRANCH MEDICAL)	
TECHNOLOGY, INC.,)	
)	
Defendant.)	

**LETTER TO THE HONORABLE CHRISTOPHER J. BURKE IN SUPPORT OF
HYPERBRANCH MEDICAL TECHNOLOGY, INC.'S MOTION TO STRIKE
PLAINTIFFS' UNTIMELY PRODUCTION OF NEW TEST RESULTS AND NEW
EVIDENCE REGARDING THE DEGRADATION OF AMIDE LINKAGES**

OF COUNSEL:

Jonathan G. Graves
Stephen C. Crenshaw
COOLEY LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190
(703) 456-8000

Adam M. Pivovar
COOLEY LLP
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004
(202) 842-7889

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Thomas C. Grimm (#1098)
Jeremy A. Tigan (#5239)
Stephen J. Kraftschik (#5623)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
tgrimm@mnat.com
jtigan@mnat.com
skraftschik@mnat.com

*Attorneys for HyperBranch Medical
Technology, Inc.*

November 27, 2017

Public Version Filed: March 23, 2018

Dear Judge Burke:

In a last ditch effort to salvage their case, Plaintiffs try again to inject untimely new evidence into this case. First, during the November 2, 2017 deposition of Plaintiffs' expert, Dr. Mays, Plaintiffs' counsel attempted to present *during cross-examination* test results that had never been disclosed in expert reports. Subsequently, on November 27th, Plaintiffs served a "Supplemental Report" by Dr. Mays discussing these new "tests." Second, Plaintiffs introduced new evidence regarding degradation of amide linkages in Dr. Mays' reply report that should have been presented in his opening expert report. HyperBranch respectfully asks the Court to strike Plaintiffs' attempt to insert this new and untimely report and evidence and to preclude Plaintiffs from relying on it.

Issue 1: Plaintiffs' new testing evidence. At the start of Dr. Mays' deposition, Plaintiffs offered to provide HyperBranch with a copy of alleged test results that were never previously disclosed during this case. (*See* Ex. A (Mays' Dep. Tr.) at 8:13-9:18.) These test results purport to be designed to "determine if there is degradation of amide bonds by visual inspection." (Ex. B (Mays Suppl. Rpt.), Ex. 3 at 1.) When HyperBranch objected to this untimely production and declined to question Dr. Mays on the purported "tests," Plaintiffs then proceeded to attempt to inject them into the case by "cross-examining" Dr. Mays on them. (Ex. A at 395:8-401:4.) Dr. Mays admitted during his deposition that the "testing" "was started just a few days before [he] submitted [his] last report in this case," (*id.* at 397:13-15), and that he *could have* performed the experiments previously but did not do so as part of his opening report because "[he] simply didn't think it was necessary. [He] thought [Plaintiffs] could prevail on the . . . basis of what was known in the literature. . . ." (*Id.* at 402:13-403:2.) Now, nearly three months after opening expert reports were due and well after the close of expert discovery, Plaintiffs served a "Supplemental" report from Dr. Mays addressing his new tests. (Ex. B.)

There is no legitimate dispute that Dr. Mays' purported "testing" and supplemental report are untimely. "[P]arties may not use their obligation to supplement [expert reports] as an excuse to violate the clear terms of a scheduling order, unilaterally buying themselves additional time to make disclosures, thereby unduly prejudicing other parties." *Intellectual Ventures I LLC v. AT&T Mobility LLC*, C.A. No. 12-193-LPS, 2017 WL 478565, at *5 (D. Del. Jan. 31, 2017). Accordingly, Dr. Mays' supplemental report (including the new test results) (Ex. B) and any testimony relating thereto at his deposition (*i.e.*, Ex. A at 395:8-403:19) should be stricken from the record, and Plaintiffs should be precluded from relying on these tests for any purpose.

Issue 2: New Evidence in Dr. Mays' Reply Report Regarding the Degradation of Amide Linkages. Dr. Mays' reply report on infringement presents new theories and evidence regarding whether amide linkages are "biodegradable groups" in the context of the asserted claims of the '5,705 patent. Specifically, this new evidence and Dr. Mays' discussion of the same are disclosed in his Reply Expert Report and Declaration. (*See* Ex. C (Mays' Reply Rpt.), ¶¶ 163-66; ¶ 169 (the last sentence and citation); ¶¶ 173-74, 182, 188-90, 193-96, 199, 201-12; ¶ 213 (the last two sentences); and Exhibits U, W, X, and Y.)

As part of his opening report on infringement, Dr. Mays analyzed whether the Accused Products meet the limitation of claim 1 of the '5,705 patent that recites "wherein the biodegradable groups of the hydrogel consist of the esters." (Ex. D (Mays' Op. Rpt.), ¶¶ 271-81.) In this regard, Dr. Mays briefly asserted that amide linkages "are stable under physiological conditions in a patient and do not substantially biodegrade." (*Id.*, ¶ 278.) In reaching this

opinion, Dr. Mays relied only on the following references: certain U.S. Patents (*id.*, ¶ 277), “a portion” of the prosecution history of US 11/653,433 (*id.*, ¶ 279 & Ex. 51), and a reference titled “The Amide Linkage: Selected Structural Aspects in Chemistry, Biochemistry, and Materials Science.” (*Id.*, ¶ 280). These references constitute the entire realm of evidence Dr. Mays used to support his infringement opinions, as he confirmed: “all the facts and data [he] considered in formulating [his] opinions” were in his opening report. (Ex. A at 87:16-88:6; 89:6-92:6.)

In his reply report, Dr. Mays departed from this cursory analysis and presented new evidence which he asserts also shows that amide linkages do not degrade. [REDACTED]

[REDACTED] Dr. Mays also relies for the first time on an article by Radzicka published in 1996 and a patent issued to HyperBranch in 2013. (*See id.*, ¶¶ 189-90 & Ex. Y; ¶¶ 193-94 & Ex. U.) Nothing prevented Dr. Mays from including this evidence in his opening report.

Dr. Mays’ presentation and discussion of this new evidence does not rebut any newly disclosed theory in HyperBranch’s rebuttal reports¹; rather, it is a blatant attempt to shore up Dr. Mays’ cursory opening opinion. This is improper for a reply report. “[E]xpert reports that simply address the same general subject matter as a previously-submitted report, but do not directly contradict or rebut the actual contents of that prior report, do not qualify as proper rebuttal or reply reports.” *Withrow v. Spears*, 967 F. Supp. 2d 982, 1002 (D. Del. 2013); *see also Glass Dimensions, Inc. ex rel. Glass Dimensions, Inc. Profit Sharing Plan & Trust v. State St. Bank & Trust Co.*, 290 F.R.D. 11, 16 (D. Mass. 2013) (finding a rebuttal expert report was in fact an untimely affirmative report, where the report discussed the “same general subject matter” as the report it was supposed to rebut). Rule 26 of the Federal Rules of Civil Procedure requires that the report of an expert witness set forth “a complete statement of all opinions the witness will express and the basis and reasons for them,” “the facts or data considered by the witness in forming them,” and “any exhibits that will be used to summarize or support them.” Fed. R. Civ. P. 26(a)(2)(B)(i)-(iii). Plaintiffs were required to provide Dr. Mays’ full infringement opinion and the evidence supporting those opinions “at the times and in the sequence that the court orders,” *i.e.*, in his opening report. Fed. R. Civ. P. 26(a)(2)(D). Because Plaintiffs failed to do so, the Court should preclude them from relying on this new evidence. Fed. R. Civ. P. 37(c)(1).

The Pennypack Analysis. In determining whether to grant this motion to strike, the Court must look to the Third Circuit’s *Pennypack* factors. *See Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904-05 (3d Cir. 1977), *overruled on other grounds by Goodman v. Lukens Steel Co.*, 777 F.2d 113 (3d Cir. 1985).

¹ [REDACTED]

[REDACTED] Dr. Mays’ Supplemental Report similarly asserts that the new “tests” rebut Dr. Lowman’s “new opinion” regarding amide bond degradation. (Ex. B ¶ 4.) But Plaintiffs have been aware of HyperBranch’s position at least since February 29, 2016, during the preliminary injunction phase of this case. (*See* D.I. 146 (Lowman Rebuttal Decl.), ¶ 126 (“[T]he mere fact that the rate of ester degradation is faster than amide degradation under physiological conditions does not thereby mean that amides are *not* hydrolytically biodegradable as Dr. Mays contends.”).)

Factors (1) and (2) regarding prejudice support granting this motion to strike. HyperBranch is extremely prejudiced by this belated injection of Dr. Mays' supplemental report, including the alleged "tests," and new evidence. HyperBranch has not had adequate time to analyze Dr. Mays' "Supplemental Report" or the new "tests," nor has it had any opportunity to prepare and provide a direct response to them. Indeed, the test results were presented so precipitously that Plaintiffs did not offer any meaningful explanation regarding the methodology, meaning, purpose, or purported relevance of the new tests until twenty-five days later, in Dr. Mays' purported "Supplemental Report." HyperBranch also has not had an opportunity to respond to the new amide degradation evidence first disclosed in Dr. Mays' reply report. In order to fully respond, HyperBranch would require fact and expert discovery on both the new tests and evidence. Fact discovery would allow HyperBranch to identify and collect factual evidence regarding amide linkage degradation and depose individuals who conducted testing on such amide linkages. Expert discovery is necessary to allow HyperBranch to depose Dr. Mays and reply to his report. Such reply would necessarily include expert opinions based on the evidence collected during supplemental fact discovery. Absent an order from the Court that reopens fact and expert discovery, HyperBranch cannot cure the prejudice it suffers and will be left with no direct affirmative rebuttal to Dr. Mays' new report, testing, and evidence.

Factor (3), regarding disruption of the trial schedule, also supports granting this motion to strike. As discussed above, permitting Dr. Mays' new report and other evidence to be injected into the case at this time would require extensive additional fact and expert discovery while the parties are in the midst of briefing dispositive motions and preparing for trial. This additional discovery simply cannot be conducted without significant disruption to the trial schedule.

Factor (4), regarding the bad faith or willfulness involved in Plaintiffs' delayed disclosure, also supports granting this motion to strike. The Third Circuit has granted motions to strike where the violation was one in a line of violations by the non-moving party. *See, e.g., In re TMI Litig.*, 193 F.3d 613, 722 (3d Cir.1999) (finding bad faith where defendants engaged in a "pattern of filings that constituted a flagrant violation" of court's orders and did not seek leave of court before filing untimely expert reports); *see also Gautier-James v. Hovenssa, L.L.C.*, Civ. No. 1:06-cv-00106, 2011 WL 4500153, at *8 (D.V.I. Sept. 27, 2011) (where, *inter alia*, a party's repeated untimely disclosures "cement[ed]" a finding of bad faith). Throughout this case, Plaintiffs have consistently withheld discovery until the last possible moment and have done so in violation of the Court's scheduling order. Plaintiffs' attempts to inject new evidence at their own expert's deposition and through an untimely "supplemental" report, as well as relying on new evidence of infringement in a reply report are the latest examples of this egregious conduct.

Factor (5), the importance of this evidence to Plaintiffs, also weighs in support of granting this motion to strike. Dr. Mays admitted that he did not perform the tests until a few days before his reply report because "[he] simply didn't think it was necessary." (Ex. A at 402:13-403:2.) Plaintiffs presented evidence in their opening expert report to address infringement and amide linkage degradation, which they can rely on in lieu of these new tests and evidence. Striking these new tests and evidence will not preclude Plaintiffs from arguing infringement. It will only require them to do so under the theories and with the evidence that they timely submitted during discovery.

Accordingly, HyperBranch respectfully requests that the Court grant its motion to strike Dr. Mays' "Supplemental Report," his new test results, and the new evidence in his reply report.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Thomas C. Grimm

Thomas C. Grimm (#1098)
Jeremy A. Tigan (#5239)
Stephen J. Kraftschik (#5623)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
tgrimm@mnat.com
jtigan@mnat.com
skraftschik@mnat.com

OF COUNSEL:

Jonathan G. Graves
COOLEY LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190
(703) 456-8000

*Attorneys for Defendant HyperBranch
Medical Technology, Inc.*

Adam M. Pivovar
James P. Hughes
Stephen C. Crenshaw
Nicholas G. Lockhart
Lisa F. Schwier
Naina Soni
COOLEY LLP
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004
(202) 842-7800

November 27, 2017
11471818

EXHIBIT A

FULLY REDACTED

EXHIBIT B

FULLY REDACTED

EXHIBIT C

FULLY REDACTED

EXHIBIT D

FULLY REDACTED